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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,046	12/05/2003	Alexander M. Harmon	022956-0235	9312
21125	7590	12/19/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			STEWART, ALVIN J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,046

Applicant(s)

HARMON ET AL.

Examiner

Alvin J. Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-13,20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-13,20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gregory US Patent 6,110,212.

Gregory discloses a biocompatible tissue implant comprising a biocompatible tissue slice having a geometry, the tissue slice including an effective amount of viable cells and further being dimensioned so that the cells can migrate out of the tissue (see Figs. 1 and 2; col. 1, lines 18-21; col. 3, lines 22-35 and lines 46-52).

Regarding claim 2, see col. 3, lines 46-52.

Regarding claims 4-6, see col. 5, lines 52-62.

Regarding claims 9, 10 and 25, the adhesive is at least one tissue layer welded by an energy source (see col. 6, lines 43-55; col. 7, lines 8-49; and col. 7, lines 59-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory US Patent 6,110,212 in view of Brauker et al US Patent 6,773,458 B1.

Gregory discloses the invention substantially as claimed. However, Gregory does not disclose minced tissue fragments.

Brauker et al teaches a tissue implant comprising at least one minced tissue fragments.

Brauker et al teaches a tissue implant comprising at least one minced tissue fragment (with a size range of about 1 mm²) containing a plurality of viable cells for the purpose of increasing the biocompatibility of the implant (see col. 13, lines 51-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Gregory reference with the Brauker et al reference in order to increase the biocompatibility of the implant.

Response to Arguments

Applicant's arguments filed September 19, 2005 have been fully considered but they are not persuasive.

The Examiner totally disagrees with the Applicant's representative point of view. The Applicants representative argues that the elastin structure is not a biological tissue and that the cells of the tissue cannot migrate out of the slice.

The Examiner wants to disclose the following points:

- First, the Applicant's representative is not positively claiming a natural occurring matrix;
- Second, the words "biological tissue slice" have been interpreted as a noun and not as a descriptive structure element;
- Third, the phrases "suitable for implantation...", "dimensioned so that the cells can migrate..." have been interpreted as functional languages. Therefore, they

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have not been given patentable weight. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Claims are being treated as product by process claims. In accordance with MPEP 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

- Fourth, the prior art reference can clearly reads on the applicants structure limitations. The Examiner wants to remind the Applicant's representative the independent claim 1 is only claiming a biological tissue slice (e.g. can be an artificial three-dimensional structure) and viable cells. Because the claim is broad, the Examiner used the Gregory reference in order to disclose the above reference is capable of having cells that can migrate out of the tissue slice because they are alive (the Gregory reference discloses living stromal cells, human cells (see col. 3, lines 46-47), etc...).
- Fifth and finally, the Gregory reference discloses in col. 1, lines 18-21 that elastin can be found in skin, blood vessels, etc.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

December 09, 2005.

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER